

SECTION 5
510(k) Summary

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Submitter Information:



This submission was prepared in July 2008 by:

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This submission was prepared for:

Terumo Cardiovascular Systems Corporation
125 Blue Ball Road
Elkton, MD 21921
Registration #1124841

Device Names/Classifications:

<u>Proprietary Name</u>	<u>Classification Name</u>	<u>Common Name</u>
Terumo ROCSafe™ Hybrid Perfusion System	Cardiopulmonary Bypass Oxygenator (Code: DTZ)	Oxygenator
	Centrifugal Pump (Non-Roller) (Code: Pump KFM)	Centrifugal Pump
	Cardiopulmonary Bypass Heat Exchanger (Code: DTR)	Heat Exchanger
	Cardiopulmonary Bypass Defoamer (Code: DTP)	Air Removal - Defoamer
	Cardiopulmonary Bypass Arterial Line Blood Filter (Code: DTM)	Arterial Filter
	Monitor, Blood-Gas, On-Line Cardiopulmonary Bypass (Code: DRY)	Cuvette - Adaptor

Predicate Device(s):

The device submitted in this 510(k) maintains characteristics that are substantially equivalent to the following devices:

- Terumo's Capiiox® RX15 Oxygenator – K062381 and K051997
- Terumo's Capiiox® RX25 Oxygenator – K062381 and K040210
- Terumo's Capiiox® Hardshell Reservoir Filter – K062381
- Sarns Centrifugal Pump – K020998
- Terumo's Capiiox® AF125X Arterial Filter – K052205
- Terumo's CDI Cuvette – K915265
- Medtronic Resting Heart System – K031700

Intended Use:

The ROCSafe™ Hybrid Perfusion System is a pre-connected extra-corporeal circuit that is designed to offer circulatory support, blood gas maintenance and blood filtration during cardiopulmonary bypass procedures lasting not more than 6-hours in duration. The ROCSafe may only be used with Terumo's System 1 Heart/Lung Pump Platform. The System includes the following:

The Capiox RX Hollow Fiber Oxygenators are intended to be used to exchange gases between blood and a gaseous environment to satisfy the gas exchange needs of a patient during cardiopulmonary bypass surgery. The integral heat exchanger is used to warm or cool blood and/or perfusion fluid as it flows through the device. The Capiox RX15 is for use with patients when the required blood flow rate will not exceed 5.0 L/min. The Capiox RX25 is for use with patients when the required blood flow rate will not exceed 7.0 L/min. The Oxygenators are intended to be used in cardiopulmonary bypass procedures that do not exceed 6 hours in duration.

The Centrifugal Pump is indicated as an extracorporeal blood pump for use in cardiopulmonary bypass procedures and is a component of the ROCSafe Hybrid Perfusion System. It is intended to propel blood through the cardiopulmonary bypass circuit. The centrifugal pump is intended to be used in cardiopulmonary bypass procedures that do not exceed 6 hours in duration.

The Capiox AF125X Arterial Line Blood Filter is intended to filter non-biologic particles and emboli and to facilitate air bubble removal from the blood flowing through the cardiopulmonary bypass circuit for up to 6 hours. The Arterial Filter is intended to be used in cardiopulmonary bypass procedures that do not exceed 6 hours in duration.

The Capiox Venous Bubble Trap is intended to facilitate the removal of air and bubbles from incoming venous blood as it flows into the extra-corporeal bypass circuit. The Bubble Trap is intended to be used in cardiopulmonary bypass procedures that do not exceed 6 hours in duration.

The CDI Cuvette is intended for use with the CDI monitor during cardiopulmonary bypass procedures when continuous monitoring of blood hematocrit, hemoglobin and oxygen saturation is desired. The Cuvettes are intended to be used in cardiopulmonary bypass procedures that do not exceed 6 hours in duration.

The blood contacting surfaces of the ROCSafe™ circuit are coated with Terumo's exclusive X-Coating surfactant that is designed to reduce the adhesion of platelets to the foreign surfaces of the circuit.

Principles of Operation and Technology:

The components included in the Terumo ROCSafe™ Hybrid Perfusion System are medical devices that have been previously cleared by the United States Food and Drug Administration in prior 510(k) applications. This particular system is a collection of those "cleared" devices that are herein being presented in a pre-assembled configuration to satisfy the needs of clinical perfusionists. As such, there has been no change in the operation or technology employed by the individual devices.

Design and Materials:

The materials that are used in the construction of the Terumo ROCSafe™ Hybrid Perfusion System includes, but not limited to, polycarbonate, stainless steel, polyvinyl chloride, polyurethane, polyester, polypropylene, polyethylene terephthalate, polyethylene and X-Coating™. These materials are the same materials that are used in the construction of the individual components that were previously cleared by FDA.

Performance Evaluations:

Clinical studies involving patients are not necessary to demonstrate substantial equivalence of the subject Terumo ROCSafe™ Hybrid Perfusion System to the individual predicate devices. The safety and performance of each of the system devices has been previously demonstrated through *in-vitro* clinically simulated studies in prior submissions, and have been found to be *substantially equivalent* to predicate devices by FDA. Those prior studies have included:

- Gas Transfer
- Effects on Blood Components (Hemolysis)
- Pressure Drop
- Mechanical Integrity
- Static Priming Volume
- Heat Exchanger Performance
- Filtration Efficiency
- Air Handling
- Tubing Connection Strength

Substantial Equivalence Comparison:

In demonstrating substantial equivalence of the ROCSafe™ Hybrid Perfusion System to predicate devices, a comparative study and/or assessment was performed in each of the following areas:

- Intended use
- Duration of use/6-hour use
- Product labeling
- Operation and technology of the devices
- Product design
- Materials used in device construction
- Design performance

Substantial Equivalence Statement:

The Terumo ROCSafe™ Hybrid Perfusion Circuit is substantially equivalent in intended use, duration of use, labeling, operation and technology, design, materials, and performance to the aforementioned predicate devices.

Additional Safety Information:

- Sterilization conditions for the ROCSafe™ Hybrid Perfusion Circuit are validated in accordance with AAMI guidelines to provide a Sterility Assurance Level (SAL) of 10^{-6} . Terumo further asserts that the ethylene oxide residues will not exceed stated or implied maximum residue limits at the time of product distribution.
- Terumo maintains biocompatibility studies as recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing." [External Communicating Devices, Circulating Blood, Limited Exposure (≤ 24 hours) Contact Duration]. The blood contacting materials were found to be biocompatible.
- The X-Coating material that is applied to the blood-contacting surfaces of the devices was evaluated in an *in-vivo* animal study conducted by Terumo Cardiovascular and Sierra Biomedical Laboratories in 1999. No adverse conditions were noted.

Conclusion:

Based upon the comparative studies and analyses, Terumo Cardiovascular Systems concludes that the Capiox ROCSafe™ Hybrid Perfusion Circuit is *substantially equivalent* to the collective use of each of the corresponding predicate devices. It is further concluded that any recognized differences noted during the assessments do not raise any new issues of patient/user safety or product effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 13 2009

Terumo Cardiovascular Systems Corp.
c/o Mr. Gary A. Courtney
Regulatory Affairs/Quality Systems Mgr.
125 Blue Ball Road
Elkton, MD 21921

Re: K082321
Terumo ROCSafe™ Hybrid Perfusion System
Regulation Number: 21 CFR 870.4360
Regulation Name: Pump, Blood, Cardiopulmonary Bypass, Non-Roller Type
Regulatory Class: Class III
Product Code: KFM
Dated: December 26, 2008
Received: December 29, 2008

Dear Mr. Courtney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

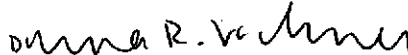
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



SECTION 4
Indications for Use

510(k) Number (if known): K082321

Device Name: Terumo ROCSafe™ Hybrid Perfusion System

Indications for Use:

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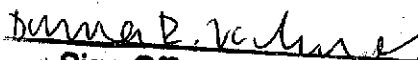
Prescription Use XX
(Part 21 CFR 801 Subpart D)

OR

Over-The-Counter Use _____
(Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


Sign-Off)
Cardiovascular Devices

K082321